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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,602	09/05/2000	Anders Carlsson	13454NP	4856

7590

09/14/2004

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/623,602

Applicant(s)

CARLSSON ET AL.

Examiner

Sharmila S. Gollamudi

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-13.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Applicant argues the terminology “prolonged” and argues that the examiner has applied hindsight. Applicant argues that Carlsson et al teach concentrating an active substance and preparing a composition that rapidly penetrates the skin to target a specific site whereas instant invention allows for the prolonged effect of the active. Applicant argues that the examiner has not rejected the claims under 35 U.S.C. 112, second paragraph for being indefinite but argues the merits of indefiniteness.

Applicant's arguments have been fully considered but they are not persuasive.

Firstly, it is pointed out that the applicant bases his arguments on the preamble, i.e. “a method of prolonging”. However, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, the methodology steps of the claims are examined since they do not depend on the preamble for completeness. Carlsson et al disclose oil-in-water emulsions containing an active agent and instant amount of galactolipid, which is applied topically. Thus, the prior art anticipates all the instant methodology steps a thorough d. Applicant has not provided any structural limitations different than the prior art's to provide applicant's composition to provide for a “prolonged” effect compared to the prior art. Therefore, since the instant claims and the prior art's method steps are the same, it is the examiner's position that the prior art inherently performs applicant's preamble.

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Secondly, the applicant has misconstrued the examiner's arguments in the last office action, the examiner did not contend nor did the examiner state that the claims are indefinite. The examiner pointed out that a specific parameter, i.e. a specific time period, was not recited in the claims. Therefore, the term "prolonged" is given its broadest reasonable interpretation. It is noted that the definition of prolong and accumulate are different. However, the examiner again points out that the duration of a drug's effectiveness is inherently increased since this accumulation allows for a continued dose at the site, which is in essence is prolonging the effective action of the drug since more drug molecules are available to provide for a longer effect. Further, Carlsson clearly states on column 4, lines 11-15 that the composition can "**sustain** a high concentration of foscarnet in the living epidermis." The examiner points out that the Webster's definition of "sustain" is to "keep up or prolong". The mere change in terminology does not extend patentability when the subject matter of the claims is not distinguishable over the prior art.

Applicant argues that the prior art teaches under Biological Tests that in fact phospholipids have a prolonged effect compared to the instant galactolipids.

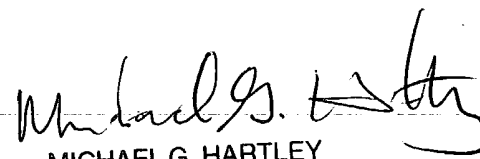
The examiner has reviewed the Biological Tests of '860, however applicant is incorrect in his assertion that Carlsson teaches that the phospholipids have a prolonged effect compared to galactolipids. In fact the examiner does not such a statement in the entire reference. The examiner notes that Carlsson states that the phospholipids provide a slower penetration of foscarnet thorough the skin on column 11, lines 60-64. Applicant's assertion that this statement means that phospholipids provide for a longer effect of an active is perplexing since the prior art is stating that the active agent did not penetrate the skin well. If an active does not penetrate the skin, it cannot have an effect, be it a long-term effect or short term. It is known that in order for a

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composition or active agent to be topically effective; an agent must penetrate the skin first.

Therefore, applicant's arguments are perplexing.

Therefore, the rejection is maintained.

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER